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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,107	08/21/2001	Lars A. Hanson	003300-723	5780

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/743,107	Applicant(s) HANSON ET AL	
	Examiner Chih-Min Kam	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54,55,61,63,64,66,68-71,73,75,76,81-97,100-103,105,106 and 110 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 54,55,66,68-71,73,75,76,81-97,100-103,105 and 106 is/are allowed.
- 6) ☒ Claim(s) 61,63,64 and 110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Claims

1. Claims 54, 55, 61, 63, 64, 66, 68-71, 73, 75-76, 81-97, 100-103, 105, 106 and 110 are pending.

Applicants' amendment filed February 27, 2006 is acknowledged, and applicants' response has been fully considered. Claims 54, 55, 61, 63, 64, 66, 68-71, 73, 100 and 101 have been amended, claims 62, 77-80, 99, 104 and 107-109 have been cancelled, and new claim 110 has been added. Therefore, claims 54, 55, 61, 63, 64, 66, 68-71, 73, 75-76, 81-97, 100-103, 105, 106 and 110 are examined.

Withdrawn-Claim Objections

2. The previous objection of claims 75-76, 81-97, 102, 103, 105 and 106 is withdrawn in view of applicants' amendment to the claim in the amendment filed February 27, 2006.

Withdrawn-Claim Rejections - 35 USC § 101

3. The previous rejection of claims 54, 55, 61-64, 66, 68-71, 73 and 99-101 under 35 U.S.C.101, is withdrawn in view of applicants' cancellation of the claim, applicants' amendment to the claim, and applicants' response at page 8 in the amendment filed February 27, 2006.

Withdrawn-Claim Rejections - 35 USC § 112

4. The previous rejection of claims 66, 104 and 107-109, under 35 U.S.C.112, first paragraph, is withdrawn in view of applicants' cancellation of the claim, applicants' amendment to the claim, and applicants' response at pages 8-9 in the amendment filed February 27, 2006.
5. The previous rejection of claims 61-64, 77-80, 99 and 107-108, under 35 U.S.C.112, second paragraph, is withdrawn in view of applicants' cancellation of the claim, applicants'

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amendment to the claim, and applicants' response at page 9 in the amendment filed February 27, 2006.

Withdrawn-Claim Rejections - 35 USC § 102

6. The previous rejection of claim 66, under 35 U.S.C. 102(b) as being anticipated by Shimazaki et al. (JP-09040578), is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 9 in the amendment filed February 27, 2006.

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 61, 63, 64 and 110 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 61, 63, 64 and 110 are directed to a purified peptide comprising SEQ ID NO:99, wherein the peptide is an amino acid sequence having (reads as comprising) GPPVSCIKR at the carboxy terminus of the peptide of SEQ ID NO: 70, 72, 73, 74, 80-83, 87-91, 93-95 or 97, wherein the peptide of SEQ ID NO: 70, 72, 73, 74, 80-83, 87-91, 93-95 or 97 may further comprise TK or EATK at the N-terminus of the sequence, and wherein the peptide of SEQ ID NO: 70, 72, 73, 74, 80-83, 87-91, 93-95 or 97 may be cyclized through a disulfide; or a purified peptide comprising SEQ ID NO:99, wherein the peptide is an amino acid sequence having TK or

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EATK at the N-terminus of the peptide of SEQ ID NO: 70, 72, 73, 74, 80-83, 87-91, 93-95 or 97.

While the specification indicates the present invention provides peptides consisting of 12 amino acids (SEQ ID NO:99; ²⁰Cys-Phe-Xaa-Xaa-Xaa-Xaa-Xaa-Xaa-Xaa-Lys-Val-Arg³¹) based on a modification of the sequence consisting of the amino acids in positions 20-31 in human lactoferrin, where Xaa in position 3 is preferably Gln or Ala, Xaa in position 4 is preferably Trp or Leu, Xaa in position 5 is preferably Gln, Lys, Orn, Ala, or Nle, Xaa in position 6 is preferably Arg, Lys or Ala, Xaa in position 7 is preferably Asn, Orn, Ala, or Nle, Xaa in position 8 is preferably Met or Leu, and Xaa in position 9 is preferably Arg or Lys. In some cases it may be advantageous to let this sequence be preceded by the sequence Thr-Lys or the longer sequence Glu-Ala-Thr-Lys (SEQ ID NO:102; page 10, lines 13-29); or peptides with the sequence of SEQ ID NO:1 (Ac-X-X-T-K-X-F-X-W-Q-R-X-M-R-K-V-R-X-X-X-X-X-X-X-X-NH₂), wherein X in position 1 is either E or no amino acid, X in position 2 is either A or no amino acid, X in position 5 is either C or A, X in position 7 is either Q or K, X in position 11 is either N or D, and X in positions 17-25 are either no amino acids at all or G-P-P-V-S-C-I-K-R (SEQ ID NO:101; page 5, lines 27-37), the specification does not disclose a genus of variants for peptides comprising GPPVSCIKR at the carboxy terminus and/or ET or EATK at the amino terminus of the peptide of SEQ ID NO: 70, 72, 73, 74, 80-83, 87-91, 93-95 or 97, where the function and the sequence of the peptides are not defined. Furthermore, there is no disclosure of any particular structure to function/activity relationship in the peptide variants, thus it is not known whether these peptides have the same function as the peptides of SEQ ID NO: 70, 72, 73, 74, 80-83, 87-91, 93-95 or 97. Without guidance on identities of peptide variants and the structure to function/activity relationship of peptide variants, one skilled in the art would not know which

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peptide variant is functional. The lack of identification of peptide variants, the lack of description of a structure to function/activity relationship for peptide variants, and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 64 is indefinite as to how the peptide of SEQ ID NO: 70, 72, 73, 74, 80-83, 87-91, 93-95 or 97 is cyclized through a disulfide bridge since these peptides contain only one cysteine in the sequence.

Conclusion

9. Claims 61, 63, 64 and 110 are rejected; and claims 54, 55, 66, 68-71, 73, 75-76, 81-97, 100-103, 105 and 106 are free of art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner



CHIH-MIN KAM
PATENT EXAMINER

CMK

May 3, 2006